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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/665,111

09/16/2003

Dolores Schendel

1406/468

6128

25297 7590 08/16/2011
JENKINS, WILSON, TAYLOR & HUNT, P. A.
3100 Tower Blvd.
Suite 1200
DURHAM, NC 27707

EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

08/16/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/665,111 | Applicant(s) SCHENDEL ET AL. |
| | Examiner KAREN CANELLA | Art Unit 1643 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25,26,33-40,42,44-46 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-53 is/are allowed.
- 6) ☒ Claim(s) 23,25,26,33-40,42 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Claim 24, 41, 47 and 49 have been canceled. Claims 23, 26, 33, 35 and 42 have been amended. Claims 50-53 have been added. Claims 23, 25, 26, 33-40, 42, 44-46, 50-53 are pending and under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25, 26, 33-40, 42, 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 23, 26 recite:

introducing proteins and/or peptides, or RNA or DNA or cDNA encoding said proteins and/or peptides into the HLA-haploidentical antigen-presenting cells,
wherein said proteins and/or peptides are overexpressed in tumor cells, or
are obtained from autologous tumor cells,
wherein said proteins and/or peptides, or RNA or DNA or cDNA encoding said proteins and/or peptides are obtained from several different tumor cell lines.

Claims 33 and 35 recite:

wherein said proteins and/or peptides are overexpressed in tumor cells, or
derived from autologous tumor cells, and
wherein said proteins and/or peptides, or RNA or DNA or cDNA encoding said proteins and/or peptides are obtained from several different tumor cell lines.

It is unclear how proteins and/or peptide, or DNA or cDNA encoding said proteins and/or peptides can be “obtained from autologous tumor cells” or “derived from autologous tumor cells” and fulfill the embodiment of being obtained from several different tumor cell lines.

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(B) It is unclear if the "tumor cells" in claims 25 and 36 is referring to the autologous tumor cells or the tumor cell lines of claims 23 and 35, respectively.

Thus the metes and bounds of claims 23, 25, 26, 33-40, 42, 44-46 are unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 23, 25, 26, 33-35, 38-40, 44, 47 and 49 under 35 U.S.C. 102(b) as being anticipated by Rhode et al (U.S. 5,869,270) is maintained for reasons or record.

Rhode et al disclose a method wherein host compatible antigen presenting cells which are haploidentical cells having the same haplotype as that of the subject (column 21, lines 46-54) are transfected with polynucleotides encoding MHC fusion proteins (abstract) . Rhodes et al disclose cDNA as a source of proteins or peptides of tumor cells (column 17, lines 19-21) which meets the limitation of proteins and/or peptides over expressed in tumor cells.. Rhodes et al disclose that antigen-presenting cells of the invention include dendritic cells (Example 16). Rhodes et al disclose that the invention provides for invoking an immune response in a mammal against a targeted disorder, such as cancer and in particular melanoma (column 23, lines 49-53). The disclosure of Rhodes et al fulfill the specific embodiments of a semi-allogeneic antigen presenting cells because an antigen presenting cell which is haploidentical includes semi-allogeneic antigen presenting cells which inherently possess one syngeneic HLA allele and one allogeneic HLA allele. Rhode et al fulfill the specific embodiments of claims 23 and 35 because the MHC fusion proteins are obtainable from autologous tumor cells as non-fused proteins and the MHC fusion proteins are "derived from" autologous tumor cells in that the non-fused proteins are obtainable from autologous tumor cells.

Claims 50-53 are free of the art.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN CANELLA whose telephone number is (571)272-0828. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571)272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAREN CANELLA/
Primary Examiner, Art Unit 1643

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